CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-669

MICROBIOLOGY REVIEW

OFFICE OF GENERIC DRUGS, HFD-640

Microbiologist's Review #2

October 5, 2000

A. 1. ANDA: 75-669

APPLICANT Faulding Pharmaceutical Co.
11 Commerce Drive
Cranford NJ 07016

2. PRODUCT NAME: Famotidine Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 10 mg/mL, Preservative-Free, single-dose, 2-mL fill in a 2-mL vial; Intravenous injection

4. METHOD OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Inhibitor of Histamine H_2-receptors

B. 1. DATE OF INITIAL SUBMISSION: July 9, 1999 (Received July 12, 1999)

2. DATE OF AMENDMENT: September 21, 2000 (Received September 22, 2000)

Subject of this Review

3. RELATED DOCUMENTS: None

4. ASSIGNED FOR REVIEW: October 5, 2000

C. REMARKS: The subject drug product is into 2-mL vials in Filling Faulding pharmaceutical facility in Aguadilla, Puerto Rico.

D. CONCLUSIONS: The submission is **recommended** for approval on the basis of sterility assurance. Specific comments regarding the process are provided in "E. Review Notes".

Paul C. DeLeo 10/23/2000

Paul C. DeLeo, Ph. D.

CSO 10/23/00

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Micro Rev.

10/23/00

Microbiology Comments to be Provided to the Applicant

ANDA: 75-669 APPLICANT: Faulding

DRUG PRODUCT: Famotidine Injection, 10 mg/ml

A. Microbiology Deficiencies:

1. Regarding environemntal monitoring, the program for exceeded limits, as described, is not clear. The criteria for decisions regarding the disposition of product were not stated.

2. Regarding sterilization and depyrogenation studies:

   a. You stated that the recent study #1051 was shown to have a 5-log reduction in endotoxin for the 13 mm rubber closures; however, the summary of the study was not provided.

   b. Please specify the production cycle for the Dispatch oven.

3. Regarding media fills:

   a. The acceptance criteria for one contaminated unit in s not acceptable in a media fill and should be lowered. See the comment in "**B.**" below.

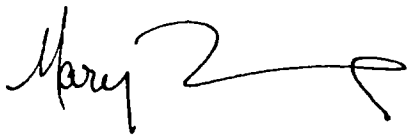
   b. The filtration studies from and Pall indicate 12 hour maximum production time. You should clarify why the media fills are only eight and nine hours long.

B. In addition to responding to the deficiencies presented above, please note and acknowledge the following comments in your response:

   You should consider lowering the acceptance criteria, for contaminated units. The statistic is not appropriate for the large quanitity of vials filled. With current technology, the acceptance criteria for media fills should be closer to "0".

Please clearly identify your amendment as "RESPONSE TO MICROBIOLOGY DEFICIENCIES". The "RESPONSE TO MICROBIOLOGY DEFICIENCIES" should also be noted in your cover page/letter.

Sincerely yours,



Mary Fanning, M.D., Ph.D.
Associate Director for Medical Affairs
Office of Generic Drugs
Center for Drug Evaluation and Research

OFFICE OF GENERIC DRUGS, HFD-640

Microbiologist's Review #1

July 17, 2000

A. 1. **ANDA** 75-669 (Review from Red Copy)

APPLICANT Faulding Pharmaceutical Co.
11 Commerce Drive
Cranford NJ 07016

2. PRODUCT NAME: Famotidine Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 10 mg/mL, Preservative-Free, single-Dose 2 mL fill in a 2 mL Vial, Intravenous

4. METHOD(S) OF STERILIZATION: **Aseptic Fill**

5. PHARMACOLOGICAL CATEGORY: Inhibitor of Histamine H_2-receptors

B. 1. DATE OF INITIAL SUBMISSION: July 9, 1999
Subject of this Review (Received, July 12, 1999)

2. DATE OF AMENDMENT: Chemistry Amendment, February 10, 2000
Subject of this Review (Received, February 11, 2000)

3. RELATED DOCUMENTS: None

4. ASSIGNED FOR REVIEW: 7/13/00

C. REMARKS: The subject drug product is aseptically filled into 2 mL vials in Building at the Faulding pharmaceutical facility in Aguadilla Puerto Rico.

D. CONCLUSIONS: The submission is not recommended for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes" and "Microbiology Comments to be Provided to the Applicant". The deficiencies noted represent Minor deficiencies.

Andrea S. High 7/17/00
Andrea S. High, Ph. D.

cc:

75-669

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micro Rev 1

7/17/00